EMERGENCY USE AUTHORIZATION OF PERAMIVIR
FACT SHEET FOR PATIENTS AND PARENTS/CAREGIVERS

The Secretary of the Department of Health and Human Services (HHS) has declared an emergency that allows for the emergency use of PERAMIVIR, an experimental drug, to treat certain people in the hospital with 2009 H1N1 (used to be called Swine Influenza A or Swine flu). PERAMIVIR is not approved by the Food and Drug Administration (FDA) for use in the United States. You can decide whether or not to receive this drug, or stop it any time. Although the use of PERAMIVIR in children has not been studied (in clinical trials), this emergency use allows PERAMIVIR to be used in children ages birth through 17 years.

Please read this Fact Sheet. It will tell you about important known and possible risks and benefits of the use of PERAMIVIR. Talk to your doctor if you have questions.

What is 2009 H1N1 flu?

2009 H1N1 flu is caused by a new H1N1 flu virus. This new virus was first found in people in the United States in April 2009. You can get 2009 H1N1 virus through contact with another person who has the virus.

What are the symptoms of 2009 H1N1 flu?

The symptoms are similar to the symptoms of regular seasonal flu and include:

- fever
- cough
- sore throat
- body aches
- headache
- chills
- tiredness (fatigue)
- runny or stuffy nose

Many people who have been infected with the 2009 H1N1 virus also had diarrhea and vomiting. Some people can have severe illness, including pneumonia and trouble breathing. Some people can die. Like seasonal flu, 2009 H1N1 flu may cause some of your other medical conditions to become worse.

What is PERAMIVIR?

PERAMIVIR is an experimental anti-viral medicine to treat certain people in the hospital with 2009 H1N1 flu. PERAMIVIR is given to you through a vein (intravenous or IV) one time each day for 5 days or more depending on what your health care provider thinks is best for you. PERAMIVIR may stop the flu virus from spreading inside your body. This may help you to get better faster.

PERAMIVIR is experimental because it is still being studied. It is not approved by FDA for use in the United States. There is limited information known about the safety and effectiveness of using PERAMIVIR to treat people in the hospital with 2009 H1N1 flu. There are no medicines approved by the FDA as safe and effective to treat people in the hospital who have the 2009 H1N1 virus.

What should I tell my healthcare provider before receiving PERAMIVIR?

Tell your healthcare provider if you

- have kidney disease
- are pregnant or plan to become pregnant
- are breast-feeding a child
- are allergic to TAMIFLU® (oseltamivir phosphate) or RELENZA® (zanamivir)

What are the possible side effects from patients receiving PERAMIVIR?

The most common side effects of PERAMIVIR are:

- diarrhea
- nausea
- vomiting
- white blood cell count decreased

These side effects may go away after you stop receiving PERAMIVIR. These are not all the possible side effects of PERAMIVIR. Peramivir is still being studied so it is possible that all of the risks are not known at this time.

Other medicines that are used to treat people with 2009 H1N1 flu have side effects that may also happen in people who receive PERAMIVIR. These side effects include:

- Signs of unusual behavior. People with the flu, especially children and adolescents, may be at a higher risk for seizures, confusion, or abnormal behavior early in their illness. These events may happen after starting PERAMIVIR or may happen if the flu is not treated. These events are not common. Patients should be watched for signs of unusual behavior.

- Allergic reaction or severe rash

Not a lot of people have taken PERAMIVIR for 5 days or longer. Serious and unexpected side effects may happen. The side effects of getting any medicine by vein are brief pain, bleeding, bruising of the skin where the needle enters, soreness and swelling at that spot, and possible infection at that spot.

Are there any risks related to pregnancy or nursing mothers?
There is no experience giving PERAMIVIR to pregnant women or nursing mothers. For a mother and fetus, the benefit of receiving PERAMIVIR may be greater than the risk from the treatment. If you are pregnant or nursing, discuss your options and specific situation with your doctor.

How do I report side effects with PERAMIVIR?
Call your healthcare provider if you have any side effects that bother you or that do not go away. You can also report side effects to **FDA MedWatch** at www.fda.gov/medwatch or call 1-800-FDA-1088.

Are there any other available treatments for people in the hospital with 2009 H1N1 flu?
Like PERAMIVIR, FDA has allowed for the emergency use of TAMIFLU® and RELENZA® to treat people in the hospital with 2009 H1N1 flu. Go to www.cdc.gov/h1n1flu/eua for information on the emergency use of TAMIFLU® and RELENZA®. TAMIFLU® and RELENZA® are not approved by FDA to treat people in the hospital with influenza virus.

What if you decide not to get PERAMIVIR?
It is your choice to be treated or not with PERAMIVIR. You can decide not to get it or stop it at any time. It will not change your regular medical care if you decide not to take it.

How can I learn more?

- ask your healthcare provider
- go to www.cdc.gov/h1n1flu/eua
- go to http://www.fda.gov/oc/opacom/hottopics/H1N1Flu/
- go to www.flu.gov